

WSA 2002 Proposed Project Plan

N01331

Project Name:	Long Term Study to Evaluate the Exposure to Smoke Constituents of Conventional Cigarettes and ECCS (JLI)-Cigarettes in Adult Smokers
Objective:	<ul style="list-style-type: none"> • Measure biomarkers of exposure in adult smokers who switch from conventional cigarettes to the JLI cigarette over a 6 month time period • Determine whether smokers who switch from low-tar cigarettes to the Accord (JLI) cigarette have a change of exposure to certain tobacco smoke constituents
Deliverable(s):	Report and Publications
Reason for Doing this Work:	To aid in the development of a reduced harm cigarette product and to contribute to the understanding of smoking and health.
Program Area: (Select One)	<input type="checkbox"/> Cancer <input type="checkbox"/> CVD <input type="checkbox"/> COPD <input type="checkbox"/> Repro <input type="checkbox"/> ETS <input type="checkbox"/> Smoking Behavior <input checked="" type="checkbox"/> Clinical Testing <input type="checkbox"/> Communication <input type="checkbox"/> Acceptability Assessment <input type="checkbox"/> R.H. Evaluation <input type="checkbox"/> R.H. Guidance <input type="checkbox"/> Non-Clinical Testing <input type="checkbox"/> Non-Clinical Research
Project Leader:	TBD

Tactics and Milestones:		Target Date:
<ul style="list-style-type: none"> • Complete contracts with CRO • Develop protocol and informed consent • Develop/refine Investigator Brochure • Submission to IRB • Begin recruitment • Study enrollment • Clinical performance • Biomarker analyses • Data base lock • Draft report • Final report 		February 15, 2002 February 25, 2002 March 1, 2002 March 20, 2002 April 1, 2002 May-June, 2002 May-December 2002 December 2002 – March 2003 April 30, 2003 May 31, 2003 June 30, 2003
Internal Resource Allocation (WSA, INBIFO)		External Resource Allocation (other PMUSA, external vendors)
H. Roethig (90 hrs); R. Kinser (150 hrs); B. Nelson (240 hrs); R. Elves (25 hrs); C. Adams (120 hrs); R. Sweeney (15 hrs); K. Totty (37.5 hrs); R. Maher (2 hrs); W. McKinney (60 hrs); K. von Holt (50 hrs); D. Newman (0 hrs)		MDSPS; Covance; ABF

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